Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed December 19, 2008. Currently, claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 remain pending. Claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has indicated that the preamble, which in this case states an intended use for the medical device namely retrieval of an intravascular device, indicates that the body of the claims refer to a medical device. The Examiner then repeats an earlier comment indicating that claims 1, 15, and 29 recite "an embolic protection filter" indicating that the embolic protection filter is a component of the medical device. This suggests that the Examiner may have overlooked the amendments of claims 1, 15, and 29 which were included with the Response submitted September 15, 2008. The lack of discussion of the §112 rejection, other than to note that Applicants believed the rejection to be inappropriate, tends to suggest that the effect of the amendment may not have been fully considered. Although the Applicants disagree with the Examiner's assertion that claims 1, 15, and 29 submitted September 15, 2008 included the intravascular device as an element, the claims in question have been amended to further prosecution. As such, this rejection is considered moot.

The Examiner has also rejected claims 1, 15, and 29 with an assertion that the specification contradicts the claim language with respect to the disposition of the braided portion relative to the distal section of the elongate shaft, whereas the proper question is whether the specification supports the claims as currently presented. The Examiner appears to have repeated the previous rejection and appears to have failed to respond to Applicant's extensive arguments in the paper filed September 15.

In each of the currently pending claims, the following language appears:

> "a braided member having a proximal portion and a distal portion, the proximal portion of the braided member coupled to the distal section of the elongated shaft member and the distal portion of the braided member extending distally of a distal end of the elongate shaft member"

This language appears to be fully supported by, for example, Figs. 2, 7, 8, and 9 and the paragraph at page 5, lines 1-16. In Fig. 2, the proximal end (46) of the braid member (32), which includes filaments (34,36) encased in an elastomeric jacket (38) can be configured to lie adjacent and flush with the distal section (16) of the elongated shaft member (12):

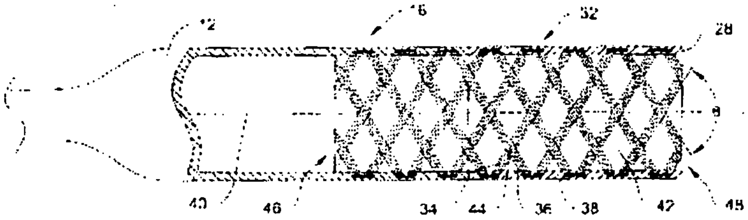

Fig. 2

Further, note that Figs. 7-9 each include a vertical line indicating the join between the distal end of the elongated shaft (12) and the proximal end of braid member (32) and those figures illustrate the expansion of the braid member (32) in response to axial compression while the flared portion of elongated shaft (12) remains substantially unchanged as the filter is engulfed. This is discussed in the paragraph at page 5, lines 1-16 in sufficient detail to support claims 1, 15, and 29. Although the Examiner characterizes the disclosure as indicating "that the entire braided member is **coupled to or integral with the flared distal section** of the elongate member" she has chosen to interpret this for examination purposes as "the braided portion extends distally of the **proximal section** of the elongated shaft member as disclosed. (Emphasis provided by the Examiner.) Applicants strongly disagree with this interpretation which would move the braid member from its attachment distal of the distal end of the elongate shaft member to a position distal of proximal section (14) of the elongate shaft which is well removed from the distal section (16) of the elongated shaft member (12) as depicted in

Fig. 1 and inconsistent with the language of the specification. Further, the passage quoted by the Examiner appears to be taken from the paragraph at page 4, lines 17-22 which reads in its entirety:

> "The distal section 16 of the elongated shaft member 12 may be flared slightly, forming a retrieval lumen 30 configured to expand and encapsulate the intravascular device therein. A braided member 32 (FIG. 2) coupled to or formed integrally with the distal section 16 may be utilized to impart flexibility to the distal portion of the retrieval device 10 while maintaining the axial stiffness and rigidity characteristics generally exhibited by the remainder of the elongated shaft member 12 ."

Read in context and in view of Fig. 2 to which it refers, it will be seen that the paragraph describes the braided member (32) as coupled to the distal portion of the elongated shaft (12) at the distal section (16) of the elongated shaft. Were the braided member, which imparts flexibility, to be extend "distally of the proximal section of the elongated shaft member" as proposed by the Examiner for examination purposes, it would appear that the braid would be present from proximal section (14) of the elongated shaft through the remaining elongated shaft (12) and continuing through the flared region adjacent to the proximal end (16) of the elongated shaft with the result that axial stiffness and rigidity characteristics desirably exhibited by the elongated shaft distal of the proximal section (14) of the elongated shaft member (12) would not be maintained.

Each of claims 1, 15, and 29 include a braided member (32) having a proximal portion and a distal portion, the proximal portion (46,48) of the braided member coupled to the distal section (16) of the elongated shaft member (12) and the distal portion of the braided member (32) extending distally of a distal end (16) of the elongate shaft member (12) as depicted in Fig. 2 and described at page 5, lines 1-16.

For at least these reasons, it is believed that the language of claims 1, 15, and 29 is not indefinite under 35 U.S.C. 112, second paragraph and is fully supported by the drawings and specification. Accordingly, Applicants respectfully request that the rejection of claims 1, 15, and 29 be withdrawn.

Claim Rejections – 35 USC § 102

Claims 1, 2, 9, 10, 15, 16, 19, and 24 were rejected under 35 U.S.C. 102(b) as anticipated by Cryer et al. (U.S. Patent No. 6,290,710), hereinafter Cryer. After careful review, Applicant must respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, *814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131).* Nowhere does Cryer appear to teach or suggest a braided member "wherein said plurality of filaments are configured to radially expand when axially compressed", as recited in claim 1.

Instead, Cryer appears to limit disclosure of "braid" to the two paragraphs at column 8, lines 1-54. The first of those two paragraphs describes braids which might be suitable for forming the filter element and does not appear relevant to a discussion of the sheath of Cryer. The second paragraph appears to discuss several alternative embodiments with somewhat mutually exclusive characteristics, for example one embodiment includes a braid which runs the entire length of the outer member while an alternative embodiment deletes the braid altogether. Of the various embodiments disclosed in the second of these paragraphs, there appears to be only one in which the material of the sheath is said to expand, even slightly, in a radial direction and that is a single component sheath, not including a braid, formed from a semi-compliant elastic material such as Pebax. That expansion does not appear to be in response to axial compression, much less axial compression of a braid. Those embodiments which do employ a braid do not appear to be configured to expand radially and the stainless steel braid employed as the only sheath braid, absent further disclosure, would not be expected to expand in a multi-layer tubing said to provide radial support in a sheath which is twice said to be of constant diameter. The Examiner has asserted, without support, that the stainless steel braid would be "inherently configured to expand when axially compressed" and further that the braid is "known to be a plurality of interwoven filaments" citing various portions of the paragraph at column 8, lines 23-54; however the paragraph does not appear to support the Examiner's assertions. Those familiar with the art will appreciate that axial compressibility of a braid is not inherent, and that attendant radial expansion, depends on characteristics of the weave, if any, associated with the braid. For example, U. S. Published Patent Application 2008/0161762 to Stehr et al., which discloses a dual braided catheter shaft, notes, "the inner braid system provides the primary axial rigidity for the desired incompressibility. Further, one familiar with braids will appreciate that the term broadly includes counter-wound helices which are not interwoven and so Cryer's use of a braid does not inherently disclose an interwoven structure. For example, U.S. Patent 6,159,187 to Park et al. discloses a "Reinforced Catheter With A Formable Distal Tip" in which, "The forming member may be a coil or coils or a woven or unwoven braid.", confirming that braids which are not interwoven are known in the art of catheters.

In those embodiments of Cryer in which the elongated shaft member is said to include a flare as required by claims 1, 15, and 29, said flare appears to be identified as elements 80 or 100 of Figs. 7-10 at the distal ends of the sheath. Accordingly, those embodiments of Cryer which do include a braid appear to do so only within the entire elongated shaft or within that portion of the shaft proximal of the optional flare 80 and do not include a separate braided member extending distally of a distal end of the elongate shaft member, the proximal portion of the braided member coupled to the distal section of the elongated shaft member, the braided member including a plurality of filaments and defining a radially expandable inner lumen wherein said plurality of filaments are configured to radially expand when axially compressed. Accordingly, Cryer does not appear to anticipate or describe *each and every element as set forth in the claim* and Applicants respectfully request that the rejection of claim 1 be withdrawn.

Additionally, for similar reasons as well as others, claims 2, 4-12, and 14, which depend from claim 1, and include significant additional limitations, are believed to be not anticipated by Cryer and Applicants respectfully request that the rejections be withdrawn.

Turning to claim 15, as discussed above, those embodiments of Cryer which do include a braid appear to do so only within the entire elongated shaft or within that portion of the shaft proximal of the optional flares 80 and 100 and do not include a separate braided member extending distally of a distal end of the elongate shaft member, the proximal portion of the braided member coupled to the distal section of the elongated shaft member, the braided member including a plurality of filaments and defining a radially expandable inner lumen. As described in claim 15, the medical device for retrieving an intravascular device includes two structurally differentiated components, an elongated shaft and a braided member, said elongated shaft having a flared distal section and said braided member coupled to the distal section of the elongated shaft and lying distal of the distal end of the elongated shaft. Outer sleeve (76) of Cryer is found in Figs. 7, 9, and 10. Flared end (80) is described as "distal end 80 of the outer sleeve may be expanded or flared" while "the sheath portion may be configured in the form of an open flare having a diameter that gradually increases toward the leading edge 80" identifying (80) as the distal end of outer sleeve (76). Thus the sheath of Cryer appears to be included within the outer sleeve (76) specifically equated by the Examiner to an elongated outer shaft of the pending claims. Within the sole paragraph of Cryer which discloses a braid in the context of the outer sleeve, the braid, if present, is present only along the entire length of the outer member or may be limited to the sheath element. In either case, the braids of Cryer appears to be present only proximal of the distal end (80) of the outer sleeve (76), said to correspond to the elongated shaft, and so cannot anticipate a braid in a differentiated element, the braided member of the claims, which is coupled to the distal section of the elongated shaft and extends distally of the distal end of the extended shaft for the reason that no differentiated element present in the disclosure of Cryer appears to occupy that position, much less to occupy that position and to include a braid which is axially compressible.

In addition to the structural deficiencies presented by the Cryer reference as discussed above, it should be noted that the filter membranes of Cryer are said to be self-expanding and so Cryer does not appear to disclose a "a medical device adapted to retrieve an embolic protection filter including a filter membrane coupled to a proximal support hoop, the support hoop defining a proximally facing opening." No support hoop appears to be present in the disclosure of Cryer. Accordingly, Cryer does not appear to anticipate or describe *each and every element as set forth in the claim* and Applicants respectfully request that the rejection of claim 15 be withdrawn.

Additionally, for similar reasons as well as others, claims 16, 18-26, 28, which depend from claim 15, and include significant additional limitations, are believed to be not anticipated by Cryer and Applicants respectfully request that the rejections be withdrawn.

Claim Rejections – 35 USC § 103

Claims 5-8, 11, 12, 20-23, 25, and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cryer. After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed above, nowhere does Cryer appear to anticipate or otherwise render obvious independent claims 1 and 15 for at least the reason that Cryer does not disclose a differentiated element which is coupled to the distal section of the elongated shaft (76) and extends distally of the distal end (80) of the extended shaft (76) for the reason that no differentiated element present in the disclosure of Cryer appears to occupy that position, much less to occupy that position and to include a braid.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Therefore, for at least these reasons, Applicant respectfully asserts that claims 5-8, 11, 12, 20-23, 25, and 26, which depend from nonobvious claims 1 and 15 respectively, are nonobvious and patentable over Cryer and Applicants respectfully request withdrawal of the rejections.

Claims 4, 18, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cryer in view of Dubrul et al. (U.S. Patent No. 6,221,006), hereinafter Dubrul. After careful review, Applicant must respectfully traverse this rejection.

As noted above, independent claims 1 and 15 are believed to be nonobvious in view of Cryer and so claims 4 and 18 which depend from claims 1 and 15 are believed to be nonobvious and Applicants respectfully request withdrawal of the rejections.

It has been shown in the discussion of independent claims 1 and 15 above, upon which reasoning the Examiner relies in rejecting claim 29, that Cryer does not appear to render obvious a medical device including a structurally differentiated element which is coupled to the distal section of the elongated shaft (76) and which extends distally of the distal end (80) of the extended shaft (76) for the reason that no differentiated element present in the disclosure of Cryer appears to occupy that position, much less to occupy that position and to include a braid. Dubrul, which appears to have been advanced for the sole purpose of providing a woven braid including a "plurality of filaments arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis and defining a radially expandable inner lumen", does not appear to remedy the structural deficiencies of Cryer because the combination would apparently simply replace the braid component of the outer sleeve Cryer, said by the Examiner to correspond to the elongated shaft of the pending claims, with a braid having a particular fabrication step. Accordingly, Applicants believe that claim 29 is patentable over Cryer in view of Dubrul for reasons similar to those discussed above in relation to claims 1 and 15 and respectfully request that the rejection be withdrawn.

Claims 14 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cryer in view of Boyle et al. (U.S. Published Patent Application No. 2003/0004537), hereinafter Boyle. After careful review, Applicant must respectfully traverse this rejection.

Claims 14 and 28 depend from claims 1 and 15 respectively which have been shown to be nonobvious under 35 U.S.C. 103. For at least this reason, it is believed that claims 14 and 28 are also nonobvious. (MPEP 2143.03) Applicants respectfully request that the rejections of claims 14 and 28 be withdrawn.

In the Response to Arguments, the Examiner has failed to address the discussion of the 112 rejection, particularly the effects of the claim amendments which were believed to render the rejections moot. Further the Examiner characterizes the 102 and 103 arguments as "that the prior art applied fails to disclose each and every element as claimed". The Examiner then attempts to assign labels to the claimed components which are incompatible with the language of the claims and the disclosure as a whole. As seen in Figs. 1 and 2, the elongated shaft member (12) terminates at reference numeral 16 distal of the flared portion of shaft (12). It may be possible that the Examiner has been misled by one aspect of the cross-sectional view of Fig. 2. The reference numeral (16) correctly indicates the point along the wall common to elongated shaft member (12) and braided member (32) at which the braid terminates at ends (46) in that particular wall cross-section. Given the nature of the braid, and as illustrated in Fig. 2, the braid ends (46) marking the proximal end of braided member (32) do not terminate in a simple circular line where the differentiated braided member (32) joins distal section (16) of elongated shaft member (12), but may be viewed as proximately terminating the braided member. For example, along the back wall of the cutaway illustrated, ends (46) which proximally terminate the braided member (32) at the join to flared distal section (16) of elongated shaft member (12) may locally exhibit a small axial offset from the boundary established by an adjacent portion of the braid in the illustrated embodiment in which the wall is continuous. Thus reference numeral (28) indicates the distal end of braided member (32) and not the distal end of distal section (16) of the distinct elongated shaft member (12) which distal section (16) terminates where the braid member (32) begins. Accordingly, the Examiner's analysis appears flawed in that she appears to believe that a braided member (32), located distal to, and coupled to, the distal most end of distal section (16) of elongated shaft member (12) does not inherently extend the braided member (32) distal of the point of attachment to distal section (16). The Examiner is mistakenly identifying the distal end (28) of the braided member (32) as the distal end of elongated shaft member (12) which end lies instead at reference numeral (16) in Fig. 2.

The Examiner has correctly noted that "nowhere does the applicant disclose that the distal portion of the braided member extends distally of the distal end 28 of the flared distal section as argued". This is simply because the Applicants would not make that assertion. Distal end (28) of the braided portion is not the distal end of the flared distal section (16) of the elongated shaft member (12). Applicants have repeatedly indicated that element (28) is the distal end of braided member (32); it is the proximal end of braided member (32) which is attached to the distal end of the flared distal region of elongated shaft (12); and element (28) lies well distal of the distal section (16) of the elongated shaft member (12). Said elongated shaft member terminates distally with the braid-free distal section (16) of the elongated shaft member (12). Note that element (28) lies well distal of element (16) in Figs. 1 and 2 and that it appears in Figs. 2 and 3 as the end of braided element (32). As seen most clearly in Fig. 3, element (28) is an end of the braided element (32). No portion of elongated shaft member (12) appears in Figure 3. It is thus unreasonable to expect to find a statement that braided member (32) extends distally from its own distal end.

The elongated shaft member and the braided member are consistently differentiated within the claims both by location and by structure throughout the claims where the braided member includes the braid and is coupled to the distal end of the elongated shaft member. End (28) is not a component of the elongated shaft member and is separated therefrom by the length of the braided member which lies distal of the elongated shaft member. As claimed, radial expansion to receive and encapsulate an intravascular device having the described characteristics occurs within the braided member. The only embodiment of Cryer in which such expansion is suggested appears to be in an elastomeric outer sleeve embodiment which does not appear to include a braid. The outer sleeve of Cryer has been identified by the Examiner as corresponding to the elongated shaft member and so the unsupported assertion that an embodiment in which the outer sleeve of Cryer contains a braid is capable of expansion appears to be irrelevant to a discussion of the expansion of a braided member, not found in Cryer. Said braided member would have to extend distally from the outer sleeve in order to correspond to the braid member of the pending claims. There does not appear to be any suggestion within Cryer that either of the embodiments in which the elongated shaft is said to include a steel braid is capable of expansion, much less that it is capable of expanding in response to axial compression, indeed the terms "compress", "compression", "compressible", and the like do not appear to be present in Cryer. Further, were the outer sleeve of Cryer to include a braid, it would not appear to anticipate or render obvious a device in which an elongated shaft member is joined to a separate braided member.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a

Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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